

REMARKS

Status of the Claims

The non-final Office Action rejects claims 1-4, 15-18, 29-32, and 43-46. By this amendment, all of the pending claims are canceled without prejudice or disclaimer and replaced with new claims 57-64.

Structure Correction

Applicants have amended paragraph [0044] of the specification to correct one of the bond positions in the lower right-hand portion of the dalbavancin structure drawing.

Response to Disclosure Objection

The disclosure is objected to as not containing the updated status of Appl. No. 10/714261. Applicants thank the Examiner for raising this matter. The present amendment is believed to adequately address the objection.

Response to Written Description Rejection

Claims 1-4, 15-18, 29-32, and 43-46 are rejected under 35 USC § 112, ¶ 1, as allegedly lacking written description. In particular, the rejection states that the claim language "wherein a content of MAG does not exceed about 4 mole percent of all dalbavancin components present" is not disclosed or suggested by the specification as originally filed.

Applicants respectfully traverse the rejection. Support for the claimed mole percent is present, e.g., at p. 12, ¶ [0045], of the specification. For at least these reasons, reconsideration and withdrawal of the rejection are therefore requested.

Response to Double Patenting Rejections

Claims 1-4, 15-18, 29-32, and 43-46 are provisionally rejected for alleged obviousness-type double patenting over claims 82-85 of Appl. No. 10/828439 and over claims 200-209 of Appl. No. 10/834395.

Without accepting the merits of the provisional rejections, Applicants are submitting herewith two terminal disclaimers covering the cited applications, and therefore respectfully request withdrawal of the rejections.

Response to Anticipation Rejections

Claims 1, 2, 15, 16, 29, 30, 43, and 44 are rejected under 35 USC § 102(b) over US Patent No. 5750509 to Malabarba et al. ("MALABARBA"). Citing col. 28, ll. 9-12, the rejection states that MALABARBA discloses a composition comprising a dalbavancin

antibiotic in combination with a stabilizer, that Applicants' claims fall within the scope thereof, and that the claimed compositions are anticipated.

Applicants respectfully traverse the rejection. Applicants claim a composition requiring, *inter alia*, (1) greater than 75 mole-percent dalbavancin factor B₀ and (2) no more than about 4 mole-percent MAG. The dependent claims more specifically recite features such as a stabilizer and different MAG and B₀ levels. As disclosed in the specification, MAG is a less active component thought to be a degradation product.

MALABARBA discloses dalbavancin and states:

Compositions . . . may take such forms as suspensions, solutions, or emulsions in oily or aqueous vehicles, and may contain formulary agents such as suspending, stabilizing and/or dispersing agents. Col. 28, ll. 9-12.

There is simply no disclosure therein of, *inter alia*, MAG itself, what MAG is, that it can be a dalbavancin degradation product, the claimed MAG level, or the claimed B₀ level. For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 15, 29, and 43 are rejected under 35 USC § 102(b) over Malabarba et al., Drugs of the Future 24(8):839-846 (1999) ("MALABARBA II"). The rejection states that MALABARBA II discloses a composition containing dalbavancin, that the claimed composition is anticipated thereby, and that the claims fall within the scope of MALABARBA II.

Applicants respectfully traverse the rejection. Just as with MALABARBA, MALABARBA II does not disclose, *inter alia*, MAG, the claimed MAG levels, or the claimed B₀ levels. For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Obviousness Rejections

Claims 1, 2, 15, 16, 29, 30, 43, and 44 are rejected under 35 USC § 103(a) over MALABARBA. The rejection states that if there is a difference in the amount of MAG present [as between MALABARBA and the claims], such would appear to be minor and would have been obvious.

Applicants respectfully traverse the rejection. The rejection does not explain how MALABARBA, which does not disclose or suggest MAG, could be seen as suggesting the claimed composition reciting, *inter alia*, minimum B₀ levels and maximum MAG levels. MALABARBA does not disclose or suggest MAG itself, and importantly, also does not disclose that MAG is a dalbavancin degradation product. This fact is relevant, *e.g.*, to whether or not the art contained even a motivation to minimize MAG. Naturally, MALABARBA also does not disclose or suggest a method of addressing a MAG problem.

As a consequence, the general reference in MALABARBA to suspending, stabilizing and/or dispersing agents, noted above, is insufficient to suggest all aspects of the present claimed invention. Accordingly, there is no suggestion therein to prepare a composition containing the claimed elements.

For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-4, 15-18, 29-32, and 43-46 are rejected under 35 USC § 103(a) over MALABARBA in view of US Patent No. 5631238 to Otake et al. ("OTAKE"). The rejection states that MALABARBA discloses dalbavancin in combination with a stabilizer but does not disclose specific stabilizers such as mannitol and lactose. Otake is cited as disclosing mannitol and lactose as conventional stabilizers. The rejection concludes that there is motivation in Otake to use mannitol and lactose as stabilizers in MALABARBA.

Applicants respectfully traverse the rejection. First, the language of the new claims does not recite mannitol or lactose, and thus the rejection is believed to be moot. Moreover, Otake, which does not pertain to dalbavancin, is not cited for and does not disclose or suggest other shortcomings of MALABARBA discussed above. For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 15, 29, and 43 are rejected under 35 USC § 103(a) over MALABARBA II. The rejection states that MALABARBA II discloses a composition containing dalbavancin and that if there is any difference in the MAG content, such would appear to be minor and obvious.

Applicants respectfully traverse the rejection. Just as with MALABARBA, MALABARBA II also does not disclose or suggest MAG, nor the claimed minimum B₀ levels and maximum MAG levels. Actually, MALABARBA II does not disclose or suggest MAG itself, and importantly, also does not disclose that MAG is an undesirable product of dalbavancin degradation. Moreover, MALABARBA II does not disclose or suggest a method of addressing a MAG impurity issue. Accordingly, there is no suggestion therein to prepare a composition containing all of the claimed elements.

For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.


Conclusion

In view of the above, Applicants respectfully submit that the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned.

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Respectfully submitted,



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